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10/565,100

08/29/2006

Nicola Frances Bateman

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9629 7590 09/05/2008
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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

09/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/565,100 | Applicant(s) BATEMAN ET AL. | |
| | Examiner PAUL DICKINSON | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3, 5, 7, 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 6 and 8-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 6/5/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Notes and Comments

In the previous office action, Claims 1, 2, 4, 6, and 8-16 were rejected under 35 U.S.C. 103(a) as unpatentable over US 5770559 in view of WO 2003072139 in further view of US 20040109890. Although this rejection is withdrawn, the Examiner would like to clarify that the citation of US 5770559 was a typographical error. The Examiner intended to cite US 5770599.

Double Patenting

Claims 1-2, 4, 6 and 8-16 are provisionally rejected on the ground of nonstatutory double patenting over claim 1-18 of copending Application No. 10505231 for the reasons set forth in the previous office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4, 6 and 8-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO9633980 (WO '980; document provided by Applicant) in view of US 6096749 ('749). WO '980 discloses 4-(3'chloro-4'fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline (the Agent), its pharmaceutical formulation, and its role

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as a tyrosine kinase inhibitor (see abstract; page 4, third paragraph; Example 27). WO '980 teaches addition of an acid, such as citric and fumaric acid (see page 7, last paragraph; Example 27; Example 32, Injection III). In one formulation, the Agent to acid weight ratio is 1:35 (see Example 32, Injection III). WO '980 teaches that the composition may be in a form suitable for oral administration, for example as a tablet or capsule (see page 19, second and third paragraphs). WO '980 teaches that pharmaceutical formulations of the Agent may be prepared by conventional manners using convention excipients (see page 19, fourth paragraph). WO '980 fails to disclose incorporation of hydroxypropylmethylcellulose.

'749 discloses tyrosine kinase inhibitors and their pharmaceutical formulations (see abstract). '749 discloses polymers such as hydroxypropylmethylcellulose and polyethylene glycol as appropriate excipients (col 16, lines 1-21). The tyrosine kinase inhibitor is present from approximately 1% to approximately 95% (see col 14, lines 65-66). In one example, the tyrosine kinase inhibitor to polyethylene glycol weight ratio is 23:1 (see Example 25; calculated from 250/11).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to incorporate hydroxypropylmethylcellulose into the formulation disclosed by WO '980, as the Agent is a tyrosine kinase inhibitor, and '749 teaches hydroxypropylmethylcellulose as an appropriate excipient for tyrosine kinase inhibitor formulations. It would have been further obvious to find the weight ratios disclosed Instant Claims 12-14 through routine experimentation, as these ratios encompass the values disclosed by WO '980 and '749. Specifically, WO '980 teaches

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an Agent to acid weight ratio of 1:35. '749 teaches a tyrosine kinase inhibitor to polyethylene glycol weight ratio of 23:1. Although the later value pertains to polyethylene glycol and not hydroxypropylmethylcellulose, the two compounds are disclosed as equivalent excipients by '749, and it would be obvious to interchange the two. See MPEP § 2144.05, II.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

September 1, 2008